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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,549	08/02/2002	Erik Nielsen	DEBE:007US	6658

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,549

Applicant(s)

NIELSEN ET AL.

Examiner

Lora E. Barnhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-23, 25, 27-30 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) 15, 17, 19-21 and 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16, 22, 23, 25 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

The examiner notes that claims 15, 17, and 19-21 have been cancelled and claims 41-43 have been added. The applicant has not, however, asserted that claims 41-43 do not add new matter and has not pointed out their basis in the specification. This Office action is directed to claims 14, 16, 22, 23, 25, 27-30, and 41-43 ONLY.

Specification

The change to the title is noted and accepted by the examiner; the objection to the title is withdrawn.

The changes to the specification have been noted and accepted by the examiner; the objection thereto is withdrawn. By way of clarification, the examiner did not mean to imply that inventor Christoforidis spells his name incorrectly, but rather that it is misspelled within the specification, for example at page 13, lines 22, 26, 32, and 34. Since this matter has no bearing on patentability, the objection is withdrawn.

The examiner has reviewed the newly submitted abstract, but asserts that it still fails to comply with M.P.E.P. chapter 600. As pointed out by the examiner, the abstract should not refer to purported merits or speculative applications of the invention. The abstract for a process invention should include the steps of said process. The abstract should be in narrative form (*i.e.* non-legal language), be clear and concise, and avoid using phrases that can be implied, such as "The present invention relates to..." The

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abstract should, in brief, describe the invention **being claimed** in plain and clear English, with particular attention paid in this case to the **claimed method steps**. The abstract should not, however, merely recite the claims word-for-word.

Election/Restrictions

Newly submitted claims 41-43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 41-43 depend from claim 36, which was withdrawn because it recites a non-elected species, specifically (k) nucleic acid.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The rejection of claims 14, 16, 22, 23, 25, and 27-30 under 35 U.S.C. 112, first paragraph, as lacking an enabling disclosure is withdrawn in view of the amendments to the claims.

The rejections of claims 14, 19, 22, and 23 under 35 U.S.C. 112, second paragraph, as being indefinite are withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

The rejections of claims 14, 19, 22, and 23 under 35 U.S.C. 102(b) as being anticipated by U.S. '995 are withdrawn in view of the amendments to the claims.

Applicant's arguments regarding U.S. '995 have been considered as they pertain to the new grounds of rejection below.

Claim Rejections - 35 USC § 103

Claims 14, 16, 22, 23, 25, and 27-30 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '995 taken in view of Touchot et al., Yao et al., and Park et al. The claims are drawn to a method of screening a substance comprising assessing the effect of said substance on a GTPase-GTPase effector interaction, wherein said GTPase is a Rab GTPase. In some dependent claims, the GTPase is selected from a list. In some dependent claims, said effect is determined in the presence of a labeled GTPase effector; this label may be radioactive or fluorescent. In some dependent claims, said effector is bound to a substrate, for example a chromatographic matrix or bead. In some dependent claims, the substance being screened is selected from a list; the elected species is β -hydroxy carboxylic acid.

As detailed in the prior action, U.S. '995 teaches a method for screening for compounds that inhibit the direct binding of Ras GTPase to its effector, Raf. In the method of U.S. '995, Raf is labeled with GST and bound to a bead, and its ability to bind soluble Ras in the presence and absence of various compounds is evaluated. U.S. '995 does not specifically teach a method for screening for compounds that affect Rab GTPase binding to Rab GTPase effectors, nor does U.S. '995 specifically teach screening β -hydroxy carboxylic acids. U.S. '995 does not teach the use of fluorescently or radioactively labeled GTPase effectors.

The applicants have asserted that the function of Rab proteins in the cell is significantly different from that of other small GTPases. The applicants have further asserted, "none of the asserted combinations of references teaches each element of the claims as presented for reconsideration". These arguments have been fully considered but are not persuasive.

The argument regarding the *in vivo* functions of Rab GTPases in signal transduction are immaterial to the assay at hand, which measures only the interaction between a given Rab GTPase and a given labeled effector. Applicants stipulate that "the interaction of a small GTPase with effectors and regulators is a conserved mechanism that can be applied for the entire family of Ras-like GTPases" (Remarks received 4/15/05, page 10, lines 2-4).

Applicant's second argument fails to comply with 37 CFR 1.111(b) because it amounts to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

The amendments to the claims do not add any new claim elements, but rather incorporate various limitations from the originally-filed claims. As such, no new grounds of rejection *per se* are required.

No claims are allowed. No claims are free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart



SANDRA E. SAUCIER
PRIMARY EXAMINER

